

PTO/SB/08A (04-02)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 4

Complete if Known

Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
SAD		US- 4,663,157	05-05-1987	Brock, E.D.	
		US- 4,699,779	10-13-1987	Palinczar, V.	
		US- 5,023,252	06-11-1991	Hsieh, D.	
		US- 5,446,025	08-29-1995	Lu, M.F.	
		US- 5,731,303	03-24-1998	Hsieh, D.	
		US- 5,891,462	04-06-1999	Carrara, D.	
		US- 6,503,894	01-07-2003	Dudley, R.E.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
SAD		AU 4998490	09-20-1990	Amway Corp.		
		AU 9141391	06-25-1992	Theratech Inc.		
		EP 189861	08-06-1986	Showa Denko		
		EP 332147	09-13-1989	Warner-Lambert		
		EP 552405	11-25-1998	Lintec Corp.		
		EP 811381	05-02-2003	Permotech N.V.		

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Sheet	2	of	4
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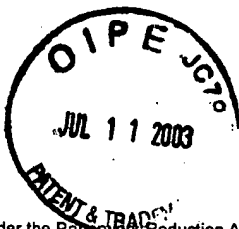
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
SA		GB 1158283	07-16-1969	Foster-Milburn		
		JP 62-011675	08-02-1994	TEZUKA		
		WO 87/03473	06-18-1987	Hsieh, D.		
		WO 92/07586	05-14-1992	Beecham Group PLC		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SAD		US- 5,730,987	03-1998	Omar	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number * Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
SAD		WO 99/24041 A1	05-20-1999	Cellegy		
		WO 96/27372 A1	09-12-1996	Int'l Medical		
		WO 93/25168 A1	12-23-1993	Theratech Inc.		

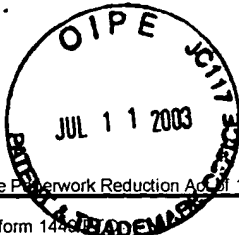
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

Sheet 3 of 4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SAD		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1996, filed on March 28, 1997.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1997, filed on March 31, 1998.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1998, filed on March 22, 1999.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1999, filed on March 14, 2000.	
		CELLEGY PHARMACEUTICALS, INC.: INVESTORS: PRESS RELEASES, "Cellegy Pharmaceuticals Receives FDA Nonapproval Letter for Fortigel," July 7, 2003, www.cellegy.com.	
		DELANOE et al., "Androgenisation of Female Partners of Men on Medroxyprogesterone Acetate/Percutaneous Testosterone Contraception," The Lancet (Feb 1984), p. 276.	
		DEMERY, A. "Contraception Masculine" Soins Gyn.-Obs.-Puer.-Ped., No. 72 (May 1987) pp. 33-38.	
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		MORGAN et al., "Enhanced Skin Permeation of Sex Hormones with Novel Topical Spray Vehicles," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1213-1218.	
SAD		MORGAN et al., "Enhanced Transdermal Delivery of Sex Hormones in Swine with a Novel Topical Aerosol," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1219-1225.	

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Signature

Date
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/046,454		
		Filing Date	October 19, 2001		
		First Named Inventor	DUDLEY, R.		
		Art Unit	1617		
		Examiner Name	JIANG, S.		
Sheet	4	of	4	Attorney Docket Number	01917581

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SJD		"PERCUTACRINE STRONG ANDROGENIC Testosterone" Percutacrine Androgenique Forte from VIDAL dictionary (1985).	✓
		POPE JR., et al., "Testosterone Gel Supplementation for Men with Refractory Depression: A Randomized, Placebo-Controlled Trial," Am. J. Psychiatry, 160(1): 105-111 (2003).	
		Protest Under 37 CFR 1.291(a) of U.S. Patent Application No. 09/651,777 dated August 20, 2002.	
SJD		SCHOOR, M., "Livening Up Libidos: Testosterone Patches Can Help Revive Women's Sex Drive," www.abcnews.com, September 6, 2000.	

Examiner Signature		Date Considered	10/14/03
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01917581

SERIAL NO.
10/046,454

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT
R. Dudley

FILING DATE
October 19, 2001

GROUP
1617

(Use several sheets if necessary)

(37 CFR 1.98 (b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER								PATENTEE	CLASS	SUB CLASS	FILING DATE
SAD	2	1	5	5	6	5	8	04/25/39	Herrman, et al.			
	3	0	6	8	1	8	8	12/11/62	Beste, et al.			
	3	2	1	8	2	8	3	11/16/65	Miller			
	3	8	8	7	6	9	9	06/03/75	Yolles			
	3	9	3	9	1	1	1	02/17/76	Schollenberger, et al.			
	4	0	0	9	2	5	4	02/22/77	Renold			
	4	0	8	3	9	7	3	04/11/78	Van der Vies			
	4	1	6	1	9	4	8	07/24/79	Bichon			
	4	4	4	7	5	6	2	05/08/84	Ivani			
	4	4	7	8	8	2	2	10/23/84	Haslam, et al.			
	4	6	3	1	1	8	8	12/23/86	Stoy, et al.			
	4	6	9	0	7	7	5	09/01/87	Schott, et al.			
	4	7	0	4	2	8	2	11/03/87	Campbell, et al.			
	4	7	2	5	4	3	9	02/16/88	Campbell, et al.			
	4	7	4	5	1	6	0	05/17/88	Churchill, et al.			
	4	7	6	7	6	2	7	08/30/88	Caldwell, et al.			
	4	7	8	0	3	2	0	10/25/88	Baker			
	4	7	8	8	0	6	2	11/29/88	Gale, et al.			
	4	9	2	0	2	0	3	04/24/90	Tang, et al.			
	4	9	4	6	8	7	0	08/07/90	Partain, III, et al.			
	4	9	8	1	6	9	6	01/01/91	Loomis, et al.			
	5	0	1	3	5	5	3	05/07/91	Southard, et al.			
	5	0	7	1	6	5	7	12/10/91	Oloff, et al.			
	5	1	5	2	9	9	7	10/06/92	Ebert, et al.			
	5	2	3	1	0	8	7	07/27/93	Thornfeldt			
	5	2	5	6	6	5	2	10/26/93	El-Rashidy			
	5	3	2	6	7	9	0	07/05/94	Thornfeldt			
	5	3	4	0	5	8	6	08/23/94	Pike, et al.			
	5	3	6	2	4	9	7	11/08/94	Yamada, et al.			
	5	4	4	6	0	7	0	08/29/95	Mantelle			
	5	4	6	0	8	2	0	10/24/95	Ebert, et al.			
	5	6	1	0	1	5	0	03/11/97	Labrie			
	5	6	2	9	0	2	1	05/13/97	Wright			
	5	6	4	1	5	0	4	06/24/97	Lee, et al.			
	5	6	4	3	8	9	9	07/01/97	Elias, et al.			
	5	6	4	8	3	5	0	07/15/97	DeLignieres			
	5	6	5	1	9	7	3	07/29/97	Moo-Young, et al.			
	5	6	5	4	3	3	7	08/05/97	Roentsch, et al.			
	5	6	5	6	2	8	6	08/12/97	Miranda, et al.			
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	5	7	2	3	1	1	4	03/03/98	Thornfeldt, et al.			
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	5	7	1	6	6	3	8	02/10/98	Touitou			
	5	7	1	9	1	9	7	02/17/98	Kanios, et al.			
	5	7	7	6	9	2	3	07/07/98	Labrie			

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PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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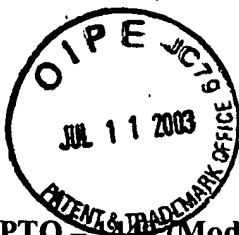
ATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454APPLICANT
R. DudleyFILING DATE
October 19, 2001GROUP
1617

(37 CFR 1.98 (b))

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500		Yu, et al., <i>Transdermal Testosterone Administration in Hypogonadal Men: Comparison of Pharmacokinetics at Different Sites of Application and at the First and Fifth Days of Application</i> , J CLIN PHARMACOL, 37:1129-1138 (1997).
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		Testoderm, PHYSICIANS' DESK REFERENCE, Alza 517-520.
500		Cunningham, et al., <i>Testosterone Transdermal Delivery System</i> , PHARMACOLOGY, BIOLOGY, AND CLINICAL APPLICATIONS OF ANDROGENS ; 42:437-447 1996 Wiley-Liss, Inc.
		Carey, et al., <i>Transdermal Testosterone Treatment of Hypogonadal Men</i> , THE JOURNAL OF UROLOGY, Vol. 140, pp. 76-79, (July 1988).
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		Brooks, et al., <i>Pharmacokinetics of Testosterone in Hypogonadal Men After Transdermal Delivery: Influence of Dose</i> , J CLIN PHARMACOL 1996; 36:732-739.
		Cofrancesco, Jr., et al., <i>Transdermal Testosterone Delivery Systems</i> , THE ENDOCRINOLOGIST, Vol. 6, No. 3, pp. 207-213.
		Mazer, et al., <i>Enhanced Transdermal Delivery of Testosterone: A New Physiological Approach for Androgen Replacement in Hypogonadal Men</i> , JOURNAL OF CONTROLLED RELEASE, 19 (1992) 347-362.
500		Schurmeyer, et al, <i>Comparative Pharmacokinetic of Testosterone Enanthate and Testosterone Cyclohexanecarboxylate as Assessed by Serum and Salivary Testosterone Levels in Normal Men</i> , INTERNATIONAL JOURNAL OF ANDROLOGY, 7 (1984) 181-187.

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Form PTO-1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617
(37 CFR 1.98 (b))			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SA	Behre, et al., <i>Testosterone Buciclate (20 Aet-1) in Hypogonadal Men: Pharmacokinetics and Pharmacodynamics of the New Long-Acting Androgen Ester</i> , JOURNAL OF ENDOCRINOLOGY AND METABOLISM, Vol. 75, No. 5, pp. 1204-1210 (1992).
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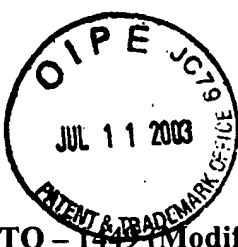
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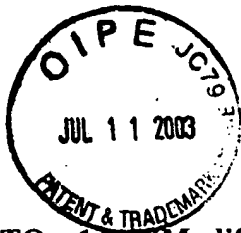
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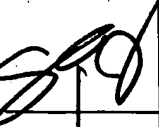




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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT R. Dudley	
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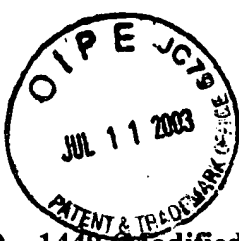
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EXAMINER INITIAL	TAB	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
SDF		6 0 3 7 3 4 6	03/14/00	Doherty, Jr., et al.			
		6 0 7 5 0 2 8	06/13/00	Graham			
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TAB	DOCUMENT NUMBER	PUB DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANSLATION
0076522	12/21/00	WO A1				
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Examiner Initials*	Date No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code * (if known)			
50		US-3888995	06/10/1975	Katz, et al.	
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[illegible]

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(37 CFR 1.98 (b))

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
SD		D. OSBORNE, ET AL., "Skin Penetration Enhancers Cited in the Technical Literature," Pharmaceutical Technology, p. pp. 58, 60, 62, 64 & 66 (November 1997).	
		International Search Report - Application No. PCT/US 01/27205, Reference No. 01736544 (International Filing Date: 08/29/2001).	
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SD		International Search Report - Application No. PCT/US 01/27199, Reference No. 01902267 (International Filing Date: 08/29/2001).	

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